SECTION 3
Summary of Safety and Effectiveness

K062935

Sponsor: RITA Medical Systems, Inc

Contact Person: Darrin Uecker
Chief Technology Officer
46421 Landing Parkway
Fremont Ca 94538
(510) 771-0440

OCT 13 2006

Summary Prepared: September 5, 2006

Trade Name: Habib 4X Laparoscopic

Common Name: Electrosurgical cutting and coagulation device and accessories

Classification: Class II per 21 CFR 878.4400

Product Code: GEI

Predicate Devices: Habib 4X (K051420)
Cool-Tip RF System (K984552)

Intended Use:

The Habib 4X Laparoscopic is intended to be used to assist in coagulation of tissue during intraoperative and laparoscopic surgical procedures

Description:

The Habib 4X Laparoscopic is a bipolar radiofrequency (RF) device that consists of a handle, an instrument shaft, and an array of four needles at the distal end of the instrument. The instrument has an attached cable which connects the device directly to the RITA Medical 1500X RF generator. The device electrodes are inserted into tissue and the tissue is coagulated using the RF power. The Habib 4X Laparoscopic is designed for use in laparoscopic surgery and the instrument shaft fits through a standard 10mm laparoscopic port. The handle includes an RF on/off switch which can be operated with either the left or right hand. The Habib 4X Laparoscopic is a single use device.

Technological Differences:

The RITA Medical Systems, Inc. Habib 4X Laparoscopic has the same technological characteristics as the Habib 4X (K051420). The configuration of the electrodes and the method

the device uses to coagulate tissues is identical. The differences are primarily to facilitate the use of the device through a laparoscopic port. The Habib 4X Laparoscopic has similar technological characteristics as the Cool-Tip RF System (K984552) in that they both use electrodes and RF energy to coagulate tissue and have the same intended use.

Performance Data:

Performance testing was done to ensure that the Habib 4 X Laparoscopic functions as intended and meets design specifications. Sufficient data was obtained to show that the device is substantially equivalent to the predicate device, and meets safety and effectiveness criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2006

Rita Medical Systems, Inc.
% Underwriters Laboratories, Inc.
Mr. Morten Simon Christensen
455 East Trimble Road
San Jose, California 95131-1230

Re: K062935
Trade/Device Name: Habib 4X Laparoscopic
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 27, 2006
Received: September 28, 2006

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

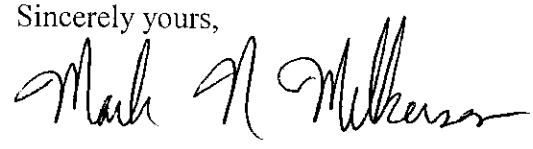
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(K) Number (if known) _____

Device Name Habib 4X Laparoscopic

The Habib 4X Laparoscopic is intended to be used to assist in coagulation of tissue during intraoperative and laparoscopic surgical procedures

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062935

Prescription Use ✓ OR Over the Counter Use _____
(per 21 CFR 801.109)